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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GUPTA, ANISH

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,637	Applicant(s) FRANCO ET AL.	
	Examiner ANISH GUPTA	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 and 40-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/20/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants amendment to the claims and the specification is acknowledged. Applicants amended claims 36, 38 and 39 were amended. Claims 1-46 are pending in this application.

2. Applicant's election of Group IX, claims 36, 38, 39 in the reply filed on 9-8-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants also elected SEQ ID NO 7 as the species for examination. The elected species was free of the prior art. However, since the claim also stated variant the claims have been examined with this limitation. Since prior art was found for variants, the claim is rejected.

Claims 36, 38, 39 and 46 are examined in this Application. Claims 1-35, 37 and 40-41 are withdrawn from consideration.

3. All rejections made in the previous office action and not cited herein are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 38, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.” Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

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“A written description of an invention involving a chemical genus, like a description of a chemical species, ‘requires a precise definition, such as by structure, formula, [or] chemical name,’ of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) (“In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . .”). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is “not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.” MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

For written description, the analysis (a) considers actual reduction to practice, (b) disclosure of drawing or structural chemical formulas, (c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed.

In the instant case, claims 38 and 39 recite metabolites derived from the nucleic acid sequence and antibodies directed to the actinomycete or the metabolites. This recitation does not provide written description for the claimed invention.

(a) actual reduction to practice/(b) disclosure of drawing or structural chemical formulas:

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The specification fails to provide any species that correspond to a metabolite or antibody. The specification states that a "metabolite" should be understood as a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. The specification fails to provide a single example of a proteinaceous or non-proteinaceous molecule that would be a metabolite for SEQ ID NO 7 or an antibody against SEQ ID NO 7.

(c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed:

The metabolites and antibodies are also defined solely by functional limitations. The specification defines "metabolite" is a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. However, the specification fails to provide any specific structures for the protein or non-protein molecules that could be construed as metabolites. Similarly, for antibodies, the specification fails for provide any relevant identifying characteristics in the way of complete/partial structure.

(d) Representative number of examples

However, the specification fails to provide a single example that would fall within the broad definition of the claimed invention for metabolites and antibodies. The definition for metabolites is all encompassing since they can include any compound that remotely has activity directly or

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indirectly to modulate the metabolism or other functional activity of the host plant. The specification does not provide a single compound, either a protein, peptide or small molecule, that would be considered a metabolite for SEQ ID NO 7. The specification simply fails to provide a representative number of species for the broad genus claimed for variants of SEQ ID NO 7, metabolites and antibodies. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Response to Arguments

Applicants argue that the specification provides one example of a metabolite form actinomycete isolation, i.e., uridote-3-acetic acid (IAA). "Moreover, considering the level of skill in the art, particularly, in relation to the metabolites expressed by a pathogen and the generation of antibodies directed to the pathogen, one skilled in the art would readily be able to isolate and identify metabolites particular from the disclosed EN16 actinomycete."

Applicant arguments have been fully considered but have not been found persuasive.

As stated in the previous office action, the description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Applicants have not provided any evidence that they were in possession of the entire genus of metabolites and antibodies. Applicants have stated that one skilled in the art would readily be able to isolate and identify metabolites. However, this does not fulfill the written description criteria. For a genus claim, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction

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to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See MPEP 2163. Here, the single examples provided neither provides relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure nor qualifies as a representative number of species by actual reduction to practice.

Thus, the rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al. (J. Gen. Plant Pathol. 66).

The claim are drawn to a variant of a nucleic acid of SEQ ID NO 7.

The reference disclose enddophytic actinomycetes as a controlling agent against fungus disease (see abstract). Note that the reference disclose that the enddophytic actinomycetes obtained exhibited broad antimicrobial activity against bacteria and yeast (see page 363). The instant

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specification defines "variant" of the subject actinomycete should be understood to mean a microorganism which exhibits at least some of the functional activity of the actinomycete of which it is a variant or mutant (see page 3 of the specification). The specification also states that the enddophytic actinomycetes exhibit antifungal activity. Since the prior art teaches enddophytic actinomycetes as a controlling agent against fungus, this is deemed to be a variant of the claimed invention.

Response to Arguments

Applicants argue that the claims have been amended and thus overcome the rejection.

Applicants arguments have been fully considered but have not been fuond persuasive.

The claims continue to recite that nucleic acid is capable of hybridizing to SEQ ID NO 7 under low stringent conditions. This limitation is still is a variant since the claimed sequence does not have to have significant homology to SEQ ID NO 7 due to the low stringent conditions. Note that the reference discloses enddophytic actinomycetes as a controlling agent against fungus. Thus, the sequence of the prior art would be capable of hybridizing SEQ ID NO 7 under low stringent conditions.

Rejection is maintained.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

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the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654